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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,900	10/30/2003	James M. Wilson	K1774CON	1181

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,900	WILSON ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *1,2,7,8,12-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6,9-11,17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/30/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/6/04,2/24/04,6/20/04,4/27/04,9/10/04,12/2/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

Claims 1-22 are pending.

It is noted that part of the amendment (pages 2-9) includes a header with the incorrect serial number. The incorrect serial number 10/696,282 is for another application and the correct number is only listed on the first page of the amendment filed on 10/26/05.

Election/Restrictions

Applicant's election of group II (claims 3-6, 9-11, 17-22) and species AAV-1 vp1 (SEQ ID NO: 13) in the reply filed on 10/26/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The request to rejoin claim 8 with the elected invention because of the amendment to the claim is not found persuasive. Rejoining claim 8 would require a search for producing a gene product in a cell either in vivo or in vitro. This would require an undue burden on the examiner to search the claim with the elected invention. In addition, claim 8 is directed to a process of using the product and the product can be used in a materially distinct method.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter

of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 1, 2, 7, 8, and 12-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/26/05.

In view of the search of the prior art, the non-elected species (SEQ ID NO: 15 and 17) are rejoined with the elected species and examined.

Specification

In view of a search in the USPTO trademark database (http://www.uspto.gov/main/trademarks.htm), MacVector appears to be a trademark.

The use of the trademark MacVector has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 18-20 are objected to because of the following informalities: MacVector is considered a trademark. Trademarks used in patents or patent applications should be entirely capitalized. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "MacVector 6.0" in claims 18-20 is a relative term which renders the claims indefinite. The term "MacVector 6.0" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term are undefined because the computer program contains an algorithm with variables and the specification does not provide what numbers were used as the variables to calculate the %identity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The claimed invention reads on a recombinant AAV vector comprising the AAV-1 3' and 5' ITRs.

The limitation in part (b) and (c) in claims 3 and 5 read on nucleotide sequences that are broader than a nucleotide sequence consisting of nucleotides 1-143 of SEQ ID NO: 1. The term "functional fragment" of (a) or (b) in either claim does not specify what function the sequence possesses and can read on a nucleic acid having any % identity to nucleotides 1-143 or 4576-4718 of SEQ ID NO: 1 of the instant invention. The term "a nucleic acid complementary to (a)" in either claim reads on a nucleic acid that has at least 1 nucleic acid that complementary to nucleotides 1-143 or 4576-4718 of SEQ ID NO: 1 of the instant invention.

The term "functional fragments thereof" of claim 9 does not specify what function the sequence possesses and can read on a nucleic acid having any % identity to SEQ ID NOs: 13, 15, or 17 of the instant invention.

In addition, the term "transgene" in either claim 3 or claim 5 does not limit the transgene to a heterologous nucleic acid encoding a protein.

Claims 3-6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava (US 5,252,479). Srivastava teaches a recombinant AAV vector comprising a nucleotide sequence that is 83.2% identical to nucleotides 1-143 of SEQ ID NO: 1 of the instant invention and cells comprising the vector (columns 17-18).

Claims 3-6, 9, and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Rutledge (GG). Rutledge teaches an AAV vector comprising a sequence wherein nucleotides

4683-4542 are 98.6% identical to nucleotides 1-143 of SEQ ID NO: 1 of the instant invention (page 312). Rutledge teaches the limitation in instant claim 9 (pages 312-314). Rutledge teaches the limitation in instant claim 11 (page 310).

Furthermore, page 24 of the instant specification recites that the AAV-6 genome taught by Rutledge 1998 (GG) seemed to be AAV-2 left ITR-AAV-2 p5 promoter-AAV-1 coding region-AAV-1 right ITR.

Claims 3-6 and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Latta et al. (6033885). Latta teaches an adenovirus comprising AAV-2 ITRs, wherein the AAV-2 ITRs comprise SEQ ID NO: 4 (columns 1 and 23) and a cell comprising the adenovirus (column 24). SEQ ID NO: 4 is 75.1% to nucleotides 1-143 of SEQ ID NO: 1 of the instant invention. Latta further teaches using AAV ITRs isolated from AAV-1 instead of AAV-2 ITRs (column 3).

Claims 3-6 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Natsoulis et al. (US 6,207,457). Natsoulis teaches a recombinant vector comprising an AAV-ITR comprising SEQ ID NO: 1 (columns 23 and 24) and cell comprising the vector. SEQ ID NO: 1 is 75.1% identical to nucleotides 4576-4718 of SEQ ID NO: 1 of the instant invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application

claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. US 6759237 (HHH). Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to a recombinant virus having an AAV-1 capsid comprising an AAV-1 vp1 having the amino acid sequence of SEQ ID NO: 13.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635